EN

PLANMECA
ProSensor
Digital Radiography System

user's manual

10019763_11

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The manufacturer, assembler, and importer are responsible for the safety, reliability and performance of the unit only if:

- installation, calibration, modification and repairs are carried out by qualified authorized personnel
- electrical installations are carried out according to the appropriate requirements such as IEC 60364
- equipment is used according to the operating instructions

Planmeca pursues a policy of continual product development. Although every effort is made to produce up-to-date product documentation this publication should not be regarded as an infallible guide to current specifications. We reserve the right to make changes without prior notice.

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1 INTRODUCTION

This manual describes how to use and install the Planmeca ProSensor sensor that is intended to be used for capturing digital intraoral x-ray images from patient's jaw, teeth, gums, roots and root canals by trained dental care professionals.

Please read this manual carefully before using the system.

Planmeca ProSensor automatically triggers and captures images to the start and end of the x-ray radiation so that any intraoral x-ray unit supporting exposure times and cones listed in tables of chapter "Exposure values for Planmeca ProSensor" can be used.

The Planmeca Romexis imaging software or third party software stating compatibility with Planmeca ProSensor or software stating compatibility through TWAIN can be used for image capturing.

Planmeca ProSensor is connected to a computer using Ethernet or USB interface and it supports Windows and MAC operating systems, see details in section "TECHNICAL SPECIFICATIONS" on page 18.

This manual is valid for following software revisions:

- Planmeca ProSensor Ethernet software version **2.1.0.R** or later
- Planmeca ProSensor USB software version **2.2.1.R** or later
- Didapi software version **4.8.1**or later.

2 SYMBOLS

Type BF equipment (Standard IEC 60601-1).

Attention, consult accompanying documents (Standard IEC 60601-1).

The use of accessory equipment not complying with the equivalent requirements of this equipment may lead to a reduced level of safety of the resulting system. Consideration relating to the choice shall include:

- use of the accessory in the Patient Vicinity
- evidence that the safety certification of the accessory has been performed in accordance to appropriate IEC60601 and/or IEC60601-1-1 harmonized national standard.

ETL CLASSIFIED

C ETL US LISTED

Intertek

3143029

Planmeca ProSensor is ETL classified and conforms to ANSI/AAMI ES60601-1 and is certified to CAN/CSA C22.2 No. 60601.1:08.

Separate collection for electrical and electronic equipment according to Directive 2002/96/EC (WEEE)

3 RELATED MANUALS

This manual should be used in conjunction with following manuals:

- Planmeca ProX User's manual (10029963)
- Planmeca Romexis User's manual (10014593)

4 SAFETY PRECAUTIONS

NOTE **The system should be operated by qualified personnel only.**

NOTE **EMC requirements have to be considered, and the equipment must be installed and put into service according to the specific EMC information provided in the accompanying documents.**

CAUTION ***Handle the Planmeca ProSensor according to the instructions given in this manual. Do not pinch the sensor or the* cable*. Do not to drop the sensor or pull strongly the sensor cable. Never cut, nick or sharply bend the sensor cable. Always advise the patient not to bite the sensor or the cable. The Planmeca limited warranty does not cover damage which is due to misuse, e.g. dropping the sensor, neglect, or any cause other than ordinary application.***

CAUTION ***Do not let the sensor cable run along the floor. Protect the cable from rolling over it with a chair or walking over it.***

CAUTION ***Do not store or use the Planmeca Sensor near (3m or 10 ft) an electrosurgical knife.***

CAUTION ***Do not unnecessarily touch the connector pins to keep them clean.***

5 SYSTEM REQUIREMENTS

NOTE The PC and other equipment connected to the system must be:

- approved by local authorities: e.g. IEC-approved (CE marked), UL / CSA approved
- located outside the patient area (more than 2m (79 in.) from the X-ray unit)
- protectively earthed.

NOTE The connection of additional equipment to a multiple portable socket-outlet must only be possible by using a tool or be supplied via separating transformer.

NOTE The multiple portable socket-outlets shall not be placed on the floor.

NOTE Make sure that the system is protected with fire wall and up-to-date anti-virus software. If possible, isolate the system from office network.

NOTE For latest up-to-date system requirements see also Planmeca website > Software > System requirements

Table 1. Planmeca Romexis system requirements

	Planmeca Romexis client work station	**Planmeca Romexis database server**
Processor	Intel Core 2 Duo 2 GHz or better	Intel Core 2 Duo 3GHz or better
RAM	3 GB	3 GB minimum
Hard disk space	80 GB	2 x 500 GB (RAID/mirroring)
Graphics card	Any integrated or dedicated	Any
USB port	USB port 2.0	USB port 2.0
Monitor	1280 x 1024	1280 x 1024
Peripherals	CD-ROM drive	CD-ROM drive
Backup medium	None necessary	DAT or equivalent
Operating system	Windows XP Pro (32 bit) Windows Vista Pro (32 or 64 bit) Windows 7 Pro (32 or 64 bit) Windows 8 Pro (32 or 64 bit) Mac OS X (Intel)*	Windows XP Pro (32 bit) Windows 2003 Server (32 or 64) Windows 2008 Server (32 or 64) Windows Vista Pro (32 or 64) Windows 7 Pro (32 or 64) Windows 8 Pro (32 or 64) Mac OS X (Intel)
Other	Java platform (Java Virtual Machine 1.6)	Java platform (Java Virtual Machine 1.6)

6 PLANMECA PROSENSOR CONTROLBOX INDICATOR LIGHT

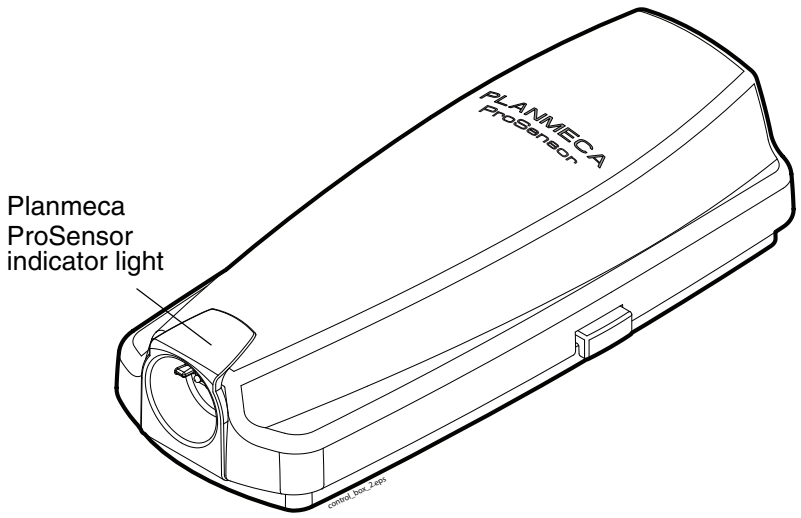


Table 2. Planmeca ProSensor ControlBox indicator light explanation

CONTROLBOX INDICATOR LIGHT	PLANMECA PROSENSOR STATUS
Off	Planmeca ProSensor system power off
Dim blue	Planmeca ProSensor system is off (not in intraoral exposure-mode and the cable is connected to the ControlBox)
Bright blue	Planmeca ProSensor system is on (Imaging program communicates with the Planmeca ProSensor system)
Slowly flashing blue	Waiting for Ready
Steady green	Waiting for Exposure
Rapidly flashing green	The exposure is taken and image is transferred from the sensor to the ControlBox
Steady red	Error mode
Slowly flashing yellow	Service mode Uploading ControlBox software
Slowly flashing blue, turns to slowly flashing dim blue, then to quickly flashing dim blue	Reading calibration files from the sensor.
Flashing violet	ControlBox startup with back-up software

NOTE The exposure can only be taken when the Planmeca ProSensor ControlBox indicator light is green and steady, not when the indicator light is flashing.

7 BEFORE EXPOSURE

NOTE **Detailed instructions for using Planmeca ProX X-ray unit and Planmeca Romexis software are given in their User's manual, which should be used in conjunction with this manual.**

NOTE **It is recommended to use a sensor holder. Select the correct sensor holder according to the type of exposure, refer to the sensor holder manual supplied with the sensor holder package.**

NOTE **In case the environment temperature reaches 40°C the sensor surface warms up to its maximum temperature of 49°C and may feel warm. The surface temperature of the sensor cools off when in patient contact.**

7.1 Positioning the patient

Ask the patient to sit down. Place a protective lead apron over the patient's chest.

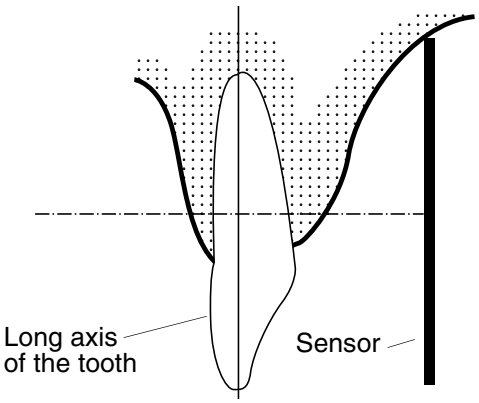
7.2 Positioning the sensor

When using the sensor for the first time the message *Loading calibration files* will appear on the Romexis window.

NOTE **When connecting the same sensor to another workstation the calibration files will be reloaded.**

Select the appropriate sensor and connect it to the Planmeca ProSensor ControlBox.

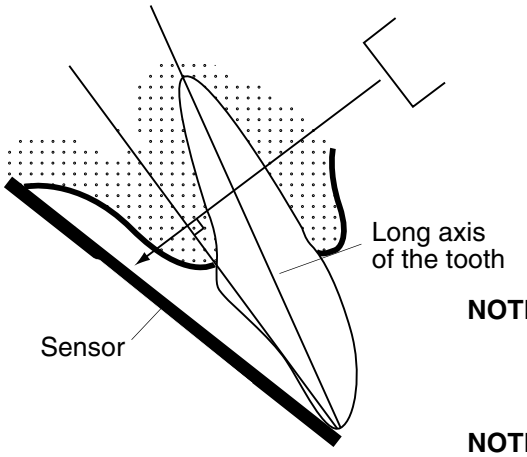
Paralleling technique (recommended)



The sensor is placed to a sensor holder which is used to align the sensor parallel to the long axis of the tooth.

Use a long cone for the paralleling technique.

Bisecting angle technique (optional)



The patient holds the sensor in place with his finger. The X-ray beam is directed perpendicularly towards an imaginary line which bisects the angle between the film plane and the long axis of the tooth.

The use of the plastic cover is not necessary because the sensor can be sterilized with liquid. The sterilization must be done after each patient.

NOTE **Be very careful not to put excessive pressure on the sensor. Do not place a clamp on the sensor. Do not take occlusal exposures with the sensor, and advise the user not to bite the sensor.**

NOTE **Never clamp the sensor package or cable with a hemostat or an unmodified "Snap-a-ray" holder.**

Make sure the Planmeca ProSensor system is ready for the exposure and communicates with Romexis (refer to section 6 "PLANMECA PROSENSOR CONTROLBOX INDICATOR LIGHT" on page 5.

On how to place the sensor into the patient's mouth refer to the sensor holder manual supplied with Planmeca ProSensor.

7.3 Selecting exposure values

Select the digital imaging mode of the unit or adjust the exposure time according to the table.

NOTE **In the digital imaging mode the highest time value that can be selected is 0.80 seconds.**

Table 3. Exposure values for Planmeca ProSensor sensors with 20 cm (8”) cones

TIME	0.01s	0.02s	0.03s	0.04s	0.05s	0.06s	0.08s	0.10s	0.12s	0.16s	0.20s	0.25s	0.32s	0.40s	0.50s	0.64s	0.80s
70 kV/ child		I	P	M	maxilla												
	I	P	M		mandible												
66 kV/ child			I	P	M	maxilla											
		I	P	M		mandible											
63 kV/ child				I	P	M	maxilla										
			I	P	M		mandible										
60 kV/ child					I	P	M	maxilla									
				I	P	M		mandible									
57 kV/ child						I	P	M	maxilla								
					I	P	M		mandible								
55 kV/ child							I	P	M	maxilla							
						I	P	M		mandible							
52 kV/ child								I	P	M	maxilla						
							I	P	M		mandible						
50 kV/ child									I	P	M	maxilla					
								I	P	M		mandible					
70 kV/ adult				I	P	M	maxilla										
			I	P	M		mandible										
66 kV/ adult					I	P	M	maxilla									
				I	P	M		mandible									
63 kV/ adult						I	P	M	maxilla								
					I	P	M		mandible								
60 kV/ adult							I	P	M	maxilla							
						I	P	M		mandible							
57 kV/ adult								I	P	M	maxilla						
							I	P	M		mandible						
55 kV/ adult									I	P	M	maxilla					
								I	P	M		mandible					
52 kV/ adult										I	P	M	maxilla				
									I	P	M		mandible				
50 kV/ adult											I	P	M	maxilla			
										I	P	M		mandible			

I INCISORS
P PREMOLARS AND CANINES
M MOLARS

Table 4. Exposure values for Planmeca ProSensor sensors with 30 cm (12”) cones

TIME	0.01s	0.02s	0.03s	0.04s	0.05s	0.06s	0.08s	0.10s	0.12s	0.16s	0.20s	0.25s	0.32s	0.40s	0.50s	0.64s	0.80s
70 kV/ child					I	P	M	maxilla									
				I	P	M		mandible									
66 kV/ child						I	P	M	maxilla								
					I	P	M		mandible								
63 kV/ child							I	P	M	maxilla							
						I	P	M		mandible							
60 kV/ child								I	P	M	maxilla						
							I	P	M		mandible						
57 kV/ child									I	P	M	maxilla					
								I	P	M		mandible					
55 kV/ child										I	P	M	maxilla				
									I	P	M		mandible				
52 kV/ child											I	P	M	maxilla			
										I	P	M		mandible			
50 kV/ child												I	P	M	maxilla		
											I	P	M		mandible		
70 kV/ adult							I	P	M	maxilla							
						I	P	M		mandible							
66 kV/ adult								I	P	M	maxilla						
							I	P	M		mandible						
63 kV/ adult									I	P	M	maxilla					
								I	P	M		mandible					
60 kV/ adult										I	P	M	maxilla				
									I	P	M		mandible				
57 kV/ adult											I	P	M	maxilla			
										I	P	M		mandible			
55 kV/ adult												I	P	M	maxilla		
											I	P	M		mandible		
52 kV/ adult									maxilla				I	P	M		
									mandible			I	P	M			
50 kV/ adult										maxilla				I	P	M	
										mandible			I	P	M		

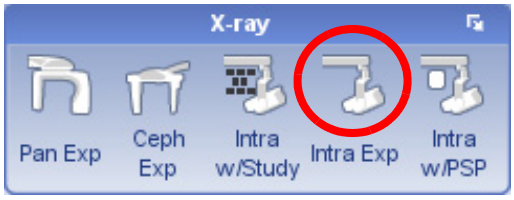
I INCISORS
P PREMOLARS AND CANINES
M MOLARS

8 CAPTURING INTRAORAL IMAGES

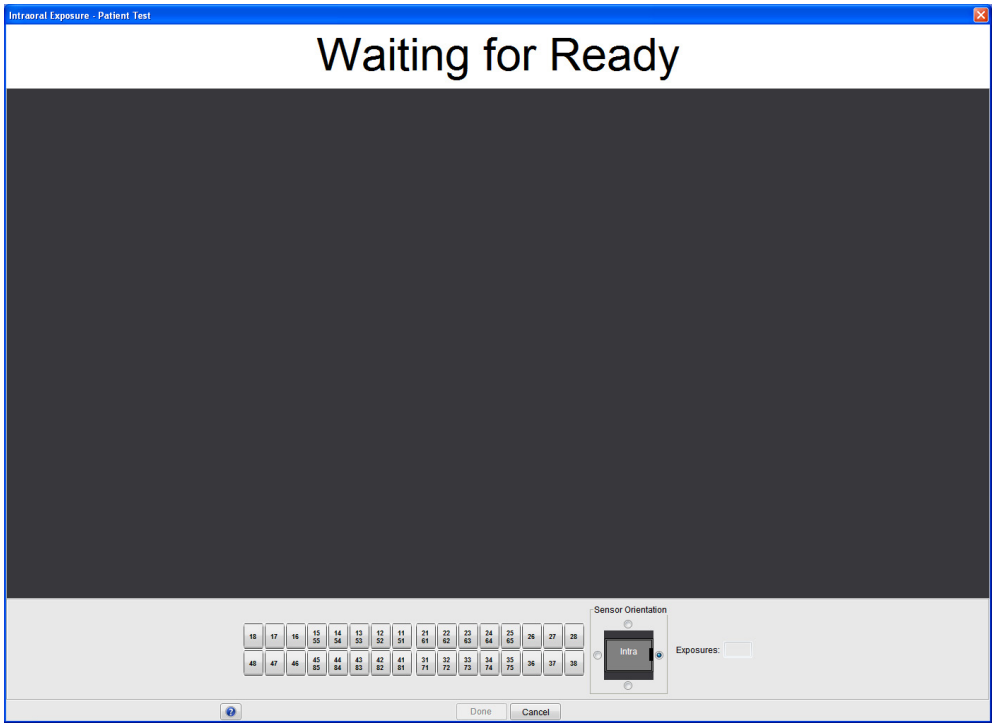
When connecting the sensor for the first time the message *Loading calibration files* will appear on the Romexis window. Also if you connect the same sensor to another workstation the files will be loaded again.

8.1 Capturing single intraoral images

1. Click the *Intraoral Exposure* button on the upper toolbar to initiate the intraoral image capture mode.



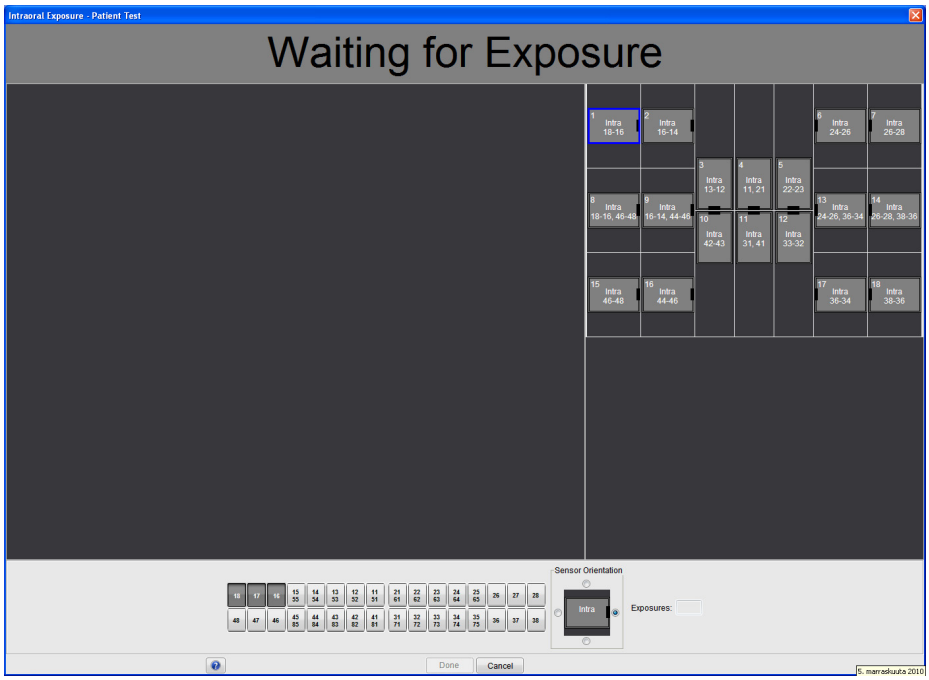
2. The *Intraoral Exposure* window appears.
3. When the X-ray unit is in ready state a message *Waiting for Ready* appears on top of the window.



4. Prepare the patient for exposure, select exposure parameters and position Planmeca ProX as required, for more information refer to Planmeca ProX user's manual.

NOTE **Inform the patient that the sensor may feel warm in the mouth.**

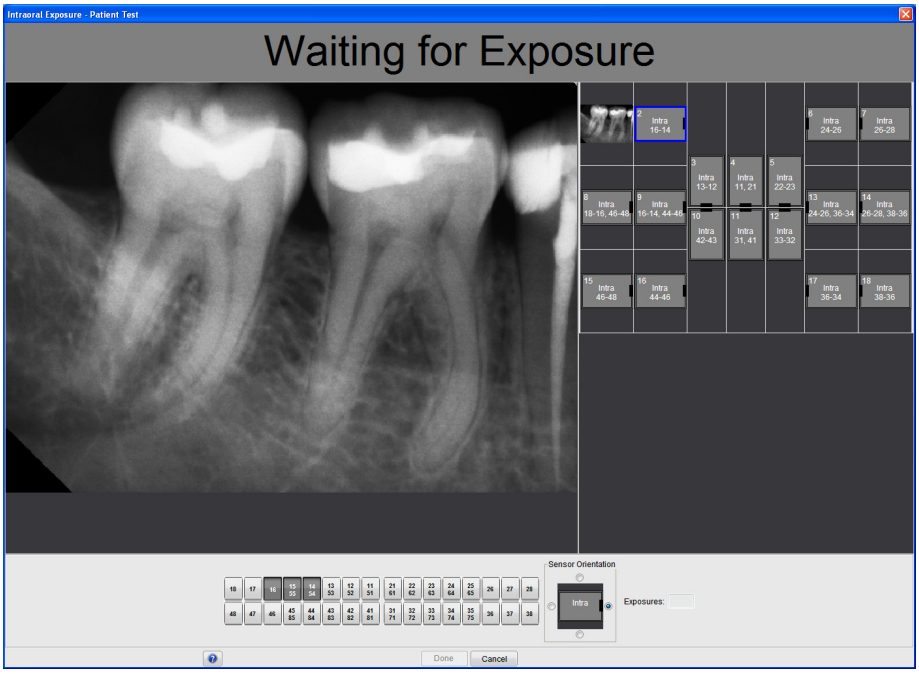
When the Planmeca ProSensor system is ready for exposure the message *Waiting for Exposure* appears on top of the window.



5. Take an exposure as usual.

   After the exposure a message stating *Saving the image* appears on the display and the image is automatically stored into the database.

6. Define the tooth numbers and sensor orientation and take the next exposure, or click *Done* to return to the ***Imaging*** module when all exposures have been captured.



NOTE **Remove the sensor from patient's mouth when all exposures have been taken.**

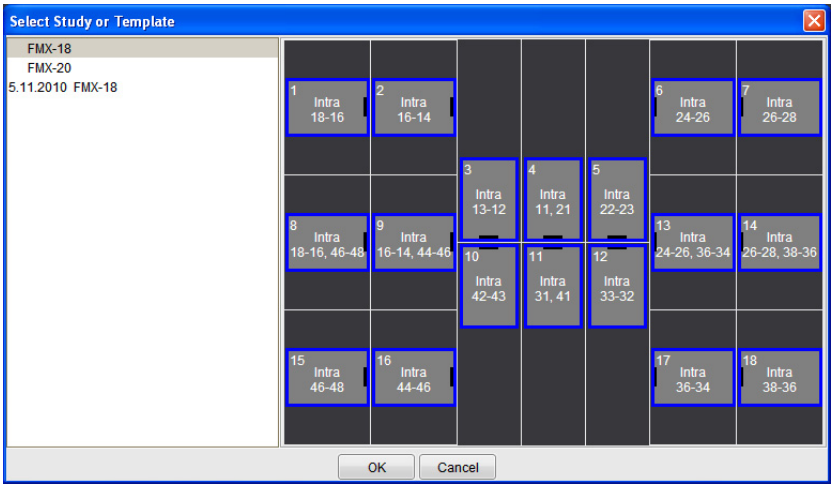
8.2 Capturing images into a study template

The images are captured into study templates containing a predefined set of multiple images.

To capture intraoral images into a study template click this button.

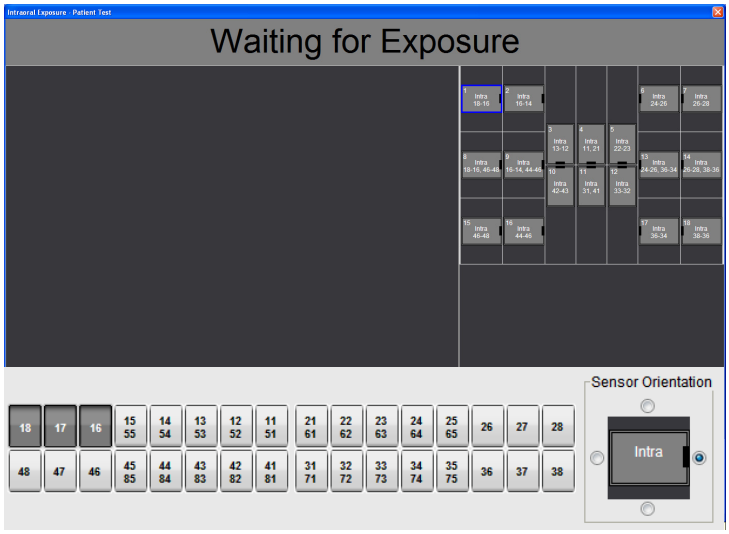
1. Select the desired study template from the list.

   At the beginning of the list there are empty templates and at the bottom of the list there are studies with dates that already include images captured earlier.



While capturing images using a template, Planmeca Romexis navigates through the template in a predefined order, denoting the current image to be captured by a blue border around the slot.

2. Follow the tooth numbering and sensor orientation as shown on the image and predefined in the template.

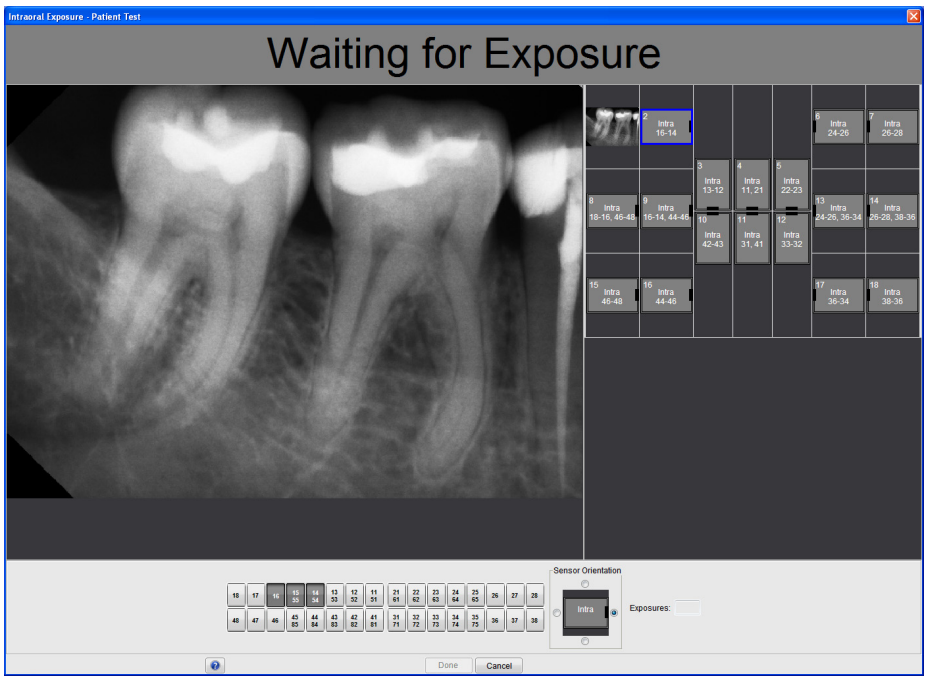


3. Prepare the patient for exposure, select exposure parameters and position Planmeca ProX as required, for more information refer to Planmeca ProX user's manual.

NOTE **Inform the patient that the sensor may feel warm in the mouth.**

When the Planmeca ProSensor system is ready for exposure the message *Waiting for Exposure* appears on top of the window. You can now expose the X-ray as usual. After the exposure a message stating *Saving the image* appears on the display and the image is automatically stored into the database.

To cancel the process click *Cancel*. The captured images are saved and the incomplete study is preserved for later use.



4. Once all images have been captured click **Done**.

NOTE **Remove the sensor from patient's mouth when all exposures have been taken.**

9 IMAGE QUALITY CONTROL

Verify the image quality after installing the software and before patient exposure. Perform quality control check according to the requirements of local authorities, using for example Quart phantom or similar.

It is recommended to regularly monitor the image quality using the same phantom according to the requirements of local authorities. See also the Constancy test manual for Planmeca Digital Intraoral X-ray System (publication number 10009324)

Before performing phantom exposures verify that the brightness and contrast settings of the monitor are accurate by using a SMPTE test pattern or similar.

9.1 Quality check using SMPTE test pattern

The test image is specified by the Society of Motion Picture and Television Engineers (www.smpte.org), and follows the SMPTE Recommended Practise RP 133-1991 Specifications for Medical Diagnostic Imaging Test Pattern for Television Monitors and Hard-Copy Recording Cameras. This image should be used for monitor setting and quality checks performed:

- Before every working day: The 5% gray field inside the 0% field and the 95% gray field inside the 100% field should be visible. If not, adjust the brightness and contrast of the monitor.
- Every month: The line raster in the corners and in the centre must be visible, the vertical and horizontal lines must form undistorted squares and the homogeneous grey background must not be coloured.

10 USING THE SENSOR HOLDERS

The sensor holders provide an easy way to position the sensor for different anatomical and diagnostic needs. For instructions how to use the sensor holders, please refer to the manual supplied with the sensor holder package.

11 CLEANING

NOTE Before cleaning the system, always check that the X-ray unit and the Planmeca ProSensor system are off (Planmeca ProSensor ControlBox indicator light is off).

11.1 Surfaces

The surfaces can be cleaned with a soft cloth damped in a mild cleaning solution.

Stronger cleaning agents can be used for disinfecting the surfaces. We recommend Dürr System-hygiene FD 333 or respective disinfecting solution.

11.2 Sensors and cables

Planmeca ProSensor sensors allow enhanced infection control in the surgery.

As the sensor casing is hermetically sealed the sensors can be immersed in disinfectant solution.

NOTE Always use appropriate instruments for cleaning the sensors.

NOTE It is mandatory to carefully follow the disinfecting and cleaning recommendations in order to not damage the sensors.

CAUTION The sensors cannot be sterilized in autoclave or UV oven.

Wipe up the sensor surface with a soft cloth damped into a disinfectant solution. The sensors can be soaked in a disinfection solution as long as there are no nicks in the cable.

The recommendable disinfectant solutions are Dürr System Hygiene FD 322 or FD 333 or similar product. The immersion time with the Dürr disinfectants is 2 minutes.

If more effective disinfection or cold sterilization is preferred for cleaning, we recommend the Johnson&Johnson Cidex Opa high level disinfectant at a minimum temperature of 20° C with maximum immersion time of 8 minutes for a reuse period not to exceed 14 days.

NOTE Follow carefully the manufacturer's recommendations on immersion time and recommended disinfectant liquids.

Do not leave the sensor in the disinfection solution overnight. The magnetic connector of the sensor cable should not be soaked.

- Use a new disposable protection cap for every sensor usage.
- Wipe up the sensor surface with a compress moisten into a sterile solution.

NOTE The sensor connector can be cleaned using a soft cloth.

11.3 Sensor holders

For cleaning the sensor holders refer to the manual supplied with the sensor holder package.

11.4 Planmeca ProSensor ControlBox

The ControlBox can be cleaned with a soft cloth damped in a mild cleaning solution.

CAUTION Switch off the unit before cleaning.

NOTE Do not disinfect the unit.

12 DISPOSAL OF PLANMECA PROSENSOR

In order to reduce the environmental load over the product's entire lifecycle, PLANMECA's products are designed to be as safe as possible to manufacture, use and dispose of.

Parts which can be recycled should always be taken to the appropriate processing centres, after hazardous waste has been removed. Disposal of obsolete systems is the responsibility of the waste possessor.

All parts and components containing hazardous materials must be disposed of in accordance with waste legislation and instructions issued by the environmental authorities. The risks involved and the necessary precautions must be taken into account when handling waste products.

Part	Main materials for disposal	Recyclable material	Waste disposal site	Hazardous waste (separate collection)
ControlBox	stainless steel	X		
- metal	ASA + PC	X		
- plastic	POM	X		
	PC		X	
	PU		X	
Cables	copper	X		
	TPE/PU		X	
Packing	cardboard,	X		
	paper,	X		
	PE foam	X		
Sensors	Return the sensors to Planmeca.			
Other parts	PoE		X	

NOTE **If the component boards cannot be recycled handle them as electronic scrap, i.e. according to the local legislation.**

13 TECHNICAL SPECIFICATIONS

Sensors

Sensor type	CMOS with scintillator

Sensor dimensions

Size 0

overall	33.6 x 23.4 mm (1.33 x 0.92 in.)
active area	25.5 x 18.9 mm (1,00 x 0,74 in.)
number of pixels	850 x 629
view delay	<5 sec.

Size 1

overall	39.7 x 25.05 (1.56 x 0.99 in.)
active area	31.5 x 20.7 (1.24 x 0.81 in.)
number of pixels	1050 x 690
view delay	<5 sec.

Size 2

overall	44.1 x 30.4 mm (1,74 x 1.2 in.)
active area	36 x 26.1 mm (1,74 x 1,2 in.)
number of pixels	1200 x 870
view delay	<5 sec.

Resolution	17 lp/mm
Theoretical resolution	33 lp/mm
Cable length	0.86 m (33.9 in.) or 2.0 m (78.7 in.)
Expected service life	10 years / 100 000 exposure cycles

Supported operating systems

Client	**Server**
Windows XP Pro (32 bit)	Windows XP Pro (32 bit)
Windows Vista Pro (32 or 64)	Windows 2003 Server (32 or 64)
Windows 7 Pro (32 or 64)	Windows 2008 Server (32 or 64)
Windows 8 Pro (32 or 64)	Windows Vista Pro (32 or 64)
Mac OS X (Intel)*	Windows 7 Pro (32 or 64)
	Windows 8 Pro (32 or 64)
	Mac OS X (Intel)

Ethernet ControlBox

Dimensions	112 x 46 x 24 mm (4.41 x 1.81 x 0.94 in.)
Power supply	48 V DC 65 mA
Cables	
ControlBox to PoE	RJ45 10m OR 15m
PoE to LAN	RJ45 10m OR 15m
Power supply	Phihong Single Port Injector Type: PSA16U-480 (POE) Input voltage 100-240 VAC (50-60 Hz) Output voltage 48VDC Max. output current 0.35 A Insulation voltage Primary-secondary 3000VDC

USB ControlBox

Dimensions	112 x 46 x 24 mm (4.41 x 1.81 x 0.94 in.)
Cables	fixed USB 2.0 power supply cable 2 or 5m (6.6 or 16.4 ft)
Power supply	Input power 2 W

Operating environment

Planmeca ProSensor is for indoor use only. The equipment is installed on the wall or on/under the table. The user moves the sensor into the operation position by hand.

The room and operation must comply with the x-ray safety shielding requirements according to radiation safety regulation in the country.

The system is used by dental care professionals.

Prior to installation of the system check that the local conditions are compatible with the appliance design.

The temperature of the operating environment should be between + 15°C and + 40°C.

The relative humidity of the operating environment should not exceed 60%.

Atmospheric pressure range should be between 700 hPa - 1060 hPa.

Transportation and storage environment

Transportation and storage temperature -10°C - +60°C.

The relative humidity during transportation and storage should not exceed 95%.

APPENDIX A: EXPOSURE VALUES FOR PLANMECA PROX

NOTE The recommended exposure values are given in Planmeca ProX User's manual section 17 "EXPOSURE VALUE TABLES".

A.1 Default exposure values

When the unit is switched on, the default exposure values appear on the displays.

Short cone exposure values			
PATIENT	**kV**	**mA**	**time**
Adult	63	6	0.125
Child	60	7	0.080

Long cone exposure values			
PATIENT	**kV**	**mA**	**time**
Adult	63	6	0.250
Child	60	7	0.200

For programming these values see the Planmeca ProX User's manual section 16.1 "Programming default exposure values"

A.2 Preprogrammed settings values

For programming these values see the Planmeca ProX User's manual, section 16.3 "Programming the preprogrammed settings".

NOTE Two sets of exposure values (time/kV/mA) have been programmed for each exposure region: one for adult mode and one for child mode.

		INCISORS			PREMOLARS AND CANINES			MOLARS		
		kV	mA	time	kV	mA	time	kV	mA	time
Adult	Maxilla	60	7	0.100	63	6	0.1	63	6	0.125
	Mandible	60	7	0.08	63	6	0.08	63	6	0.100
Child	Maxilla	60	7	0.063	60	7	0.08	60	7	0.100
	Mandible	60	7	0.05	60	7	0.064	60	7	0.080

		OCCLUSAL EXPOSURE			ENDODONTIC			BITE-WING		
		kV	mA	time	kV	mA	time	kV	mA	time
Adult	Maxilla	70	6	0.100	60	7	0.100	60	7	0.100
	Mandible	70	6	0.100						
Child	Maxilla	66	6	0.080	60	7	0.080	60	7	0.080
	Mandible	66	6	0.080						

When using the 30 cm long cone program see Planmeca ProX User's manual section 17 "EXPOSURE VALUE TABLES" or select three steps darker density (longer exposure time).

		INCISORS			PREMOLARS AND CANINES			MOLARS		
		kV	mA	time	kV	mA	time	kV	mA	time
Adult	Maxilla	60	7	0.200	63	6	0.200	63	6	0.250
	Mandible	60	7	0.160	63	6	0.160	63	6	0.200
Child	Maxilla	60	7	0.125	60	7	0.160	60	7	0.200
	Mandible	60	7	0.100	60	7	0.125	60	7	0.160

		OCCLUSAL EXPOSURE			ENDODONTIC			BITE-WING		
		kV	mA	time	kV	mA	time	kV	mA	time
Adult	Maxilla	70	6	0.200	60	7	0.200	60	7	0.200
	Mandible	70	6	0.200						
Child	Maxilla	66	6	0.125	60	7	0.160	60	7	0.160
	Mandible	66	6	0.125						

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